

Systematic Direct Angioplasty and Stent-Supported Direct Angioplasty Therapy for Cardiogenic Shock Complicating Acute Myocardial Infarction: In-Hospital and Long-Term Survival

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Objectives. This prospective observational study was conducted to examine the apparent impact of a systematic direct percutaneous transluminal coronary angioplasty (PTCA) strategy on mortality in a series of 66 consecutive patients with acute myocardial infarction (AMI) complicated by cardiogenic shock, and to analyze the predictors of outcome after successful direct PTCA.

Background. Previous studies have reported encouraging results with PTCA in patients with AMI complicated by cardiogenic shock, but a biased case selection for PTCA may have heavily influenced the observed outcomes.

Methods. All patients admitted with AMI were considered eligible for direct PTCA, including those with the most profound shock, and no upper age limit was used. The treatment protocol also included stenting of the infarct-related artery for a poor or suboptimal angiographic result after conventional PTCA.

Results. Between January 1995 and March 1997, 364 consecutive patients underwent direct PTCA, and in 66 patients AMI was complicated by cardiogenic shock. In patients with cardiogenic shock, direct PTCA had a success rate of 94%; an optimal

angiographic result was achieved in 85%; primary stenting of the infarct-related artery was accomplished in 47%; and the in-hospital mortality rate was 26%. Univariate analysis showed that patient age, chronic coronary occlusion and completeness of revascularization were significantly related to in-hospital mortality. The mean follow-up period was 16 ± 8 months. Survival rate at 6 months was 71%. Comparison of event-free survival in patients with a stented or nonstented infarct-related artery suggests an initial and long-term benefit of primary stenting.

Conclusions. Systematic direct PTCA, including stent-supported PTCA, can establish a Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow in the great majority of patients presenting with AMI and early cardiogenic shock. High performance criteria, including new devices such as coronary stents, should be considered in randomized trials where mechanical revascularization therapy is being tested.

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Patients with cardiogenic shock account for a large proportion of deaths from acute myocardial infarction (AMI). Since 1988, several observational studies (1-10) have reported encouraging results with percutaneous transluminal coronary angioplasty (PTCA) in patients with AMI complicated by cardiogenic shock. In-hospital and long-term survival is enhanced in patients with successful revascularization, but it is possible that biased case selection for PTCA had a favorable effect on survival (11). The outcomes observed may have been heavily influenced by variations in the criteria for the diagnosis of shock, the selection criteria for angiography and revascularization procedures, type of treatment received (i.e., fibrinolytic agents and mechanical support devices) and time from symp-

tom onset to treatment. Therefore, a reevaluation of direct PTCA results and of the outcome predictors in a homogeneous sample of patients with cardiogenic shock is appropriate. In our tertiary referral center, the systematic care for AMI includes direct PTCA in all patients presenting with AMI. This prospective observational study was conducted 1) to examine the apparent impact of direct PTCA on mortality in a series of 66 consecutive patients with AMI complicated by cardiogenic shock, and 2) to analyze the clinical, angiographic and procedural predictors of outcome after successful direct PTCA.

Methods

Study patients. Between January 1995 and March 1997, 374 patients with AMI eligible for direct PTCA were admitted to our center. Six patients, all without cardiogenic shock, refused PTCA, and four patients with cardiogenic shock died before they could reach the catheterization laboratory. Thus, altogether 364 patients with AMI underwent direct PTCA, and in 66 patients (18%) the infarction was complicated by early

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Abbreviations and Acronyms

AMI	= acute myocardial infarction
CABG	= coronary artery bypass graft surgery
ECG	= electrocardiogram, electrocardiographic
GUSTO	= Global Utilization of Streptokinase and TPA for Occluded Coronary Arteries (trial)
OR	= odds ratio
PTCA	= percutaneous transluminal coronary angioplasty
SHOCK	= Should We Emergently Revascularize Occluded Coronaries for Cardiovascular Shock? (trial)
TIMI	= Thrombolysis in Myocardial Infarction

cardiogenic shock. Inclusion criteria for direct PTCA were 1) chest pain persisting >30 min with ST segment elevation on the electrocardiogram (ECG) ≥ 0.1 mV in two or more contiguous leads; 2) admission within 6 h of symptom onset, as well as admission between 6 and 24 h in patients with evidence of continuing ischemia; and 3) no fibrinolytic treatment administered. Angiographic exclusion criteria for direct PTCA were 1) infarct-related artery diameter stenosis <70%, and 2) inability to identify the infarct-related artery. Patients with septal or papillary muscle rupture were not considered eligible for direct PTCA, whereas patients with prior coronary artery surgery or the usual contraindications to thrombolytic therapy were included, and no upper age limit was used.

Cardiogenic shock was defined as systolic blood pressure <90 mm Hg (without inotropic or intraaortic balloon support) that was thought to be secondary to cardiac dysfunction and associated with signs of end-organ hypoperfusion such as cold or diaphoretic extremities or altered mental status or anuria. A diagnosis of cardiogenic shock was to be confirmed at cardiac catheterization by the measurement of systolic blood pressure <90 mm Hg and left ventricular filling pressure ≥ 20 mm Hg.

Treatment protocol. Patients were pretreated with aspirin, and heparin (10,000 U) was administered immediately after sheath insertion. All patients received intravenous pressor agents or intraaortic balloon pump therapy. The decision on whether to use intraaortic balloon pump therapy was made by an experienced interventional cardiologist, and the intraaortic balloon was placed in the operating room under fluoroscopic control in nearly all cases.

Direct PTCA was always attempted whatever the coronary anatomy, and the revascularization procedure also included nonelective stenting of the infarct-related artery in patients with a nonoptimal angiographic result after one or more dilations with appropriately sized balloons. Elective stenting—that is, stenting after an optimal angiographic result achieved by conventional angioplasty—was allowed. Direct PTCA and coronary stenting were accomplished with standard techniques, including high pressure (≥ 14 atm) balloon inflation to expand the stent after deployment.

After PTCA, patients were treated with aspirin (300 mg), ticlopidine (500 mg), intravenous heparin (adjusted to keep the partial thromboplastin time to nearly 2 times control) and vasopressor agents as needed.

Angiographic analysis. Quantitative coronary angiography was performed with an automatic edge detection system (Siemens Hicor II). Coronary flow in the infarct-related artery before and after revascularization was graded according to Thrombolysis in Myocardial Infarction (TIMI) study group flow classification (12). Collateral flow before direct angioplasty was graded using the classification developed by Rentrop et al. (13). A successful revascularization procedure was defined as a residual stenosis <50% associated with TIMI grade 2 or 3 flow. An optimal immediate angiographic result was defined as a residual stenosis <30% associated with TIMI grade 3 flow. A suboptimal angiographic result was defined as TIMI grade 3 flow associated with a residual stenosis >30%, or TIMI grade 2 flow associated with a residual stenosis <50%. Unsuccessful PTCA was defined as TIMI grade flow <2 at any level of residual stenosis.

Follow-up. All patients surviving cardiogenic shock underwent clinical follow-up after hospital discharge and were scheduled to return for follow-up catheterization at 6 months. Patients were seen in the outpatient clinic 1, 3 and 6 months after discharge. After 6 months, clinical information was obtained directly from the patient (at the outpatient clinic or by telephone interview) or from the referring physician.

Statistics. Categorical data are presented as number (percentage), and continuous data as mean value \pm SD or as median value. The Fisher exact test or chi-square test analysis was used to compare categorical variables. A two-tailed Student *t* test was used to test differences among continuous variables. Survival curves were generated by using the Kaplan-Meier method. Survival curves were compared by the log-rank method. Logistic regression analysis was used to examine independent predictors of in-hospital death. Factors analyzed included age; gender; time to reperfusion; infarct location; evidence of prior myocardial infarction; presence of multivessel disease, chronic coronary occlusion or collateral vessels; infarct-related artery stenting; optimal or suboptimal immediate angiographic result; intraaortic balloon counterpulsation; and completeness of revascularization at discharge, defined as no remaining stenosis >50%. A *p* value < 0.05 was considered significant. Statistical tests were performed by using GB-STAT system (Dynamic Microsystems).

Results

Baseline clinical and angiographic characteristics (Table 1). There were significant differences between patients with shock and the entire group of those without shock. The former had a significantly higher incidence of clinical factors associated with an adverse outcome, such as greater age, female gender, previous infarction and anterior myocardial infarction. As expected, the incidence of multivessel disease, left anterior descending infarct-related artery and chronic coronary occlusion was higher in patients with than in those without shock. The shock group also included four patients with acute left main trunk occlusion. The incidence of collateral flow (Rentrop grade 2 or 3) to the infarct area was higher in patients

Table 1. Comparison of Baseline Clinical and Angiographic Characteristics of 364 Patients With and Without Cardiogenic Shock Treated With Direct PTCA

	With Shock (n = 66)	Without Shock (n = 298)	p Value
Age (yr)			
Mean	65 ± 11	62 ± 12	0.023
Range	40-82	28-89	
>75 yr	15 (23%)	40 (13%)	0.056
Male	43 (65%)	239 (80%)	0.008
Diabetes mellitus	11 (17%)	38 (13%)	0.399
Prior myocardial infarction	17 (26%)	27 (9%)	< 0.001
Exertional angina	15 (23%)	38 (13%)	0.038
Unstable angina	17 (26%)	99 (33%)	0.239
Systolic blood pressure (mm Hg)*	74 ± 13	129 ± 25	< 0.001
Infarct location			
Anterior	48 (73%)	153 (51%)	0.002
Inferior	18 (27%)	137 (46%)	0.005
Lateral	0	8 (3%)	0.178
Infarct-related artery			
LAD	44 (67%)	153 (51%)	0.024
RCA	17 (26%)	120 (40%)	0.027
LCx	1 (1%)	25 (9%)	0.049
Left main trunk	4 (6%)	0	< 0.001
Multivessel disease	44 (67%)	147 (49%)	0.011
Chronic occlusion	27 (41%)	26 (9%)	< 0.001
Restrop grade 2 or 3 collateral flow	4 (6%)	38 (13%)	0.124

*Measured at cardiac catheterization. Data are presented as mean value ± SD or number (%) of patients in group. LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery.

without shock, but this difference is not significant. All patients had shock at initial assessment or within 1 h after admission.

Procedural data (Table 2). There were no differences in time from symptom onset to reperfusion between groups. The median time from AMI onset to reperfusion was 3.3 h.

Direct PTCA was attempted in all patients. The direct PTCA success rate was 94% for patients with shock and 98% for patients without shock ($p = 0.038$), and an optimal immediate angiographic result was achieved more frequently in the latter group (85% and 96%, respectively, $p = 0.001$). Primary PTCA failure occurred in four patients with shock. All four patients with cardiogenic shock and failed PTCA died; two of the four were referred for emergency surgery, and died after coronary artery bypass grafting (CABG), and the other two died in the catheterization laboratory during attempted PTCA. The incidence of primary stenting of the infarct-related artery was similar in the patients with (47%) and without (48%) shock. Patients with cardiogenic shock needed multiple stent implantation more frequently as a result of more severe and diffuse disease of the infarct artery (21% vs. 15%, $p = \text{NS}$ [0.278]). Stenting was elective in 7 patients (24%) and non-elective because of a nonoptimal result after PTCA in 22 (76%). A total of 43 stents were placed in patients with shock: 22 Gianturco-Roubin stents (Cook Inc.), 16 Palmaz-Schatz stents (J & J Interventional Systems), and 5 Microstents

Table 2. Procedural Characteristics in Patients With and Without Cardiogenic Shock

	With Shock (n = 66)	Without shock (n = 298)	p Value
Time from AMI onset to reperfusion (h)	3.6 ± 1.5	3.4 ± 1.7	0.520
Median time to reperfusion (h)	3.3	3.3	
PTCA failure	4 (6%)	5 (2%)	0.038
PTCA success	62 (94%)	293 (98%)	0.038
Optimal angiographic result	56 (85%)	285 (96%)	0.001
Suboptimal angiographic result	6 (9%)	8 (3%)	0.014
Stenting of the IRA*	29 (47%)	140 (48%)	0.885
Multiple stent implantation*	13 (21%)	45 (15%)	0.278
Multivessel revascularization*	6 (10%)	6 (2%)	0.005
PTCA	2 (3%)	3 (1%)	
CABG	4 (6%)	3 (1%)	
IABP	47 (71%)	20 (7%)	< 0.001
Intubation	10 (15%)	0	< 0.001

*For patients with PTCA success: n = 62 with shock; n = 293 without shock. Data are presented as mean value ± SD, median or number (%) of patients in group. AMI = acute myocardial infarction; CABG = coronary artery bypass graft surgery; IABP = intraaortic balloon counterpulsation; IRA = infarct-related artery; PTCA = percutaneous transluminal coronary angioplasty.

(AVE). Short stents or coiled stents were used when a difficult negotiation could be predicted from anatomic characteristics of the vessel. At least one stent was successfully deployed in all cases attempted. Additional stents could not be deployed in two patients with dissection distal to one successfully deployed stent. PTCA of noninfarct arteries was successfully performed in two patients with cardiogenic shock and severe (>70% stenosis) multivessel disease, and four patients with hemodynamically stable multivessel disease were referred for elective CABG before discharge. Overall, 10% of patients with cardiogenic shock needed percutaneous or surgical multivessel revascularization, whereas only 2% of patients without shock had in-hospital multivessel revascularization ($p = 0.005$). Intraaortic balloon pump therapy was administered in 47 patients with (76%) and in 20 patients without (7%) shock ($p < 0.001$). Nineteen patients with cardiogenic shock did not have intraaortic balloon placement because they had severe atherosclerotic disease or tortuosity of the iliac arteries and the systolic blood pressure could be supported at >80 mm Hg by intravenous pressor agents.

In-hospital outcome of patients with cardiogenic shock (Tables 3 and 4). In 66 patients with cardiogenic shock the mortality rate was 26% (17 of 66). In patients with successful PTCA the mortality rate was 21% (13 of 62). In the group without shock the mortality rate was 0.7% (2 of 298, $p < 0.001$). In patients with successful PTCA, progressive deterioration in the setting of refractory cardiogenic shock was the most frequent cause of death (6 patients); the other causes of death in the remaining hemodynamically stabilized patients were respiratory failure (2 patients), fatal reinfarction (2 patients), a ruptured chronic aortic aneurysm (1 patient) and vascular complications of intraaortic balloon pumping (2 patients died after vascular surgery). Reocclusion of the infarct-

Table 3. In-Hospital Outcome of 66 Patients With Cardiogenic Shock

	No. (%) of Patients
Primary failure (n = 4)	
Death	4 (100%)
Successful PTCA (n = 62)	62 (94%)
Death	13 (21%)
Refractory shock	6 (10%)
Respiratory failure	2 (3%)
Reinfarction	2 (3%)
Vascular complications	3 (5%)
Recurrent ischemia	6 (10%)
Recurrent ischemia or reinfarction	8 (13%)
Patients with stenting (n = 29)	1 (3%)
Patients without stenting (n = 33)	7 (21%)
Emergency repeat PTCA	6 (10%)
Overall mortality	17 (26%)

PTCA = percutaneous transluminal coronary angioplasty.

related artery occurred in 8 (13%) of the 62 patients with cardiogenic shock. Two of the 62 had a fatal reinfarction (including 1 patient with a stented infarct-related artery), and 6 patients (10%) had recurrent ischemia. Recurrent ischemia occurred only in patients without primary stenting. Repeat PTCA was successfully performed in all patients with recurrent ischemia, and all but one patient with recurrent ischemia underwent bailout stenting of the infarct-related artery. Overall, recurrent ischemia or reinfarction occurred more frequently in patients without than in patients with a stented infarct-related artery (21% vs. 3%, $p = 0.040$).

Univariate analysis of factors associated with in-hospital mortality in patients with cardiogenic shock and successful PTCA (Table 4) demonstrated that age (odds ratio) [OR] = 1.077, $p = 0.040$), chronic coronary occlusion (OR = 4.235, $p = 0.032$) and completeness of revascularization (OR = 0.068, $p = 0.013$) were significantly related to in-hospital

Table 5. Six-Month Clinical and Angiographic Follow-Up of 49 In-Hospital Survivors

	No. (%) of Patients
Clinical follow-up	
Death	2 (4%)
Nonfatal reinfarction	2 (4%)
Repeat PTCA	4 (8%)
Cardiac surgery	3 (6%)
NYHA functional class I or II	39 (80%)
Angiographic follow-up	
Eligible for 6-month angiography	37 (76%)
Coronary angiography performed	34 (92%)
Patency	31 (91%)
Reocclusion	3 (9%)
Restenosis	10 (29%)

NYHA = New York Heart Association; PTCA = percutaneous transluminal coronary angioplasty.

mortality. The mean age was 63 years among survivors and 70 years among nonsurvivors. The mortality rate of patients >75 years old was 36%. Anterior location of the current infarction was not related to in-hospital mortality. Among patients with inferior infarction, seven were identified as having right ventricular involvement by ECG criteria. There was no difference between the mortality rate of patients with right ventricular infarction and that of patients without right ventricular involvement (29% vs. 20%, $p = 0.682$). By multivariate analysis, no collected clinical and angiographic variable remained as an independent predictor of in-hospital outcome.

Follow-up (Table 5). The 49 patients surviving cardiogenic shock had a mean clinical follow-up period of 16 ± 8 months. The survival rate at 6 months was 71% (Fig. 1). During the 6-month period, there were two deaths and two nonfatal reinfarctions. Four patients with recurrent ischemia and significant restenosis of the infarct-related artery underwent repeat PTCA, whereas three underwent cardiac surgery

Table 4. Univariate Logistic Regression Analysis of Clinical, Angiographic and Procedural Characteristics Relevant to In-Hospital Mortality of 62 Patients With Cardiogenic Shock and Successful Direct PTCA

	Survivors (n = 49)	Nonsurvivors (n = 13)	OR	95% CI	p Value
Age (yr)	63 ± 11	70 ± 10	1.077	1.003-1.157	0.040
Female gender	17 (35%)	4 (30%)			0.791
Time to reperfusion (h)	3.6 ± 1.5	3.2 ± 2.0			0.364
Anterior AMI	36 (73%)	9 (69%)			0.761
Prior infarction	11 (22%)	5 (38%)			0.247
Multivessel disease	29 (59%)	12 (92%)			0.051
Chronic occlusion	17 (35%)	9 (69%)	4.235	1.135-15.8	0.032
Retrop grade 2 or 3 collateral flow	4 (8%)	—			0.314
Stenting	23 (47%)	6 (46%)			0.960
Suboptimal result	6 (12%)	—			0.327
IABP	35 (71%)	8 (62%)			0.494
Completeness of revascularization	27 (55%)	1 (8%)	0.068	0.008-0.564	0.013

Data are presented as mean value ± SD or number (%) of patients in group. CI = confidence interval; OR = odds ratio; other abbreviations as in Table 2.

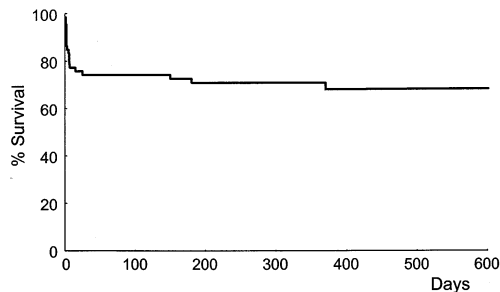


Figure 1. Actuarial survival of 66 patients with AMI complicated by cardiogenic shock who were treated by direct PTCA.

(CABG in one, left ventricular aneurysmectomy without bypass grafting in one and heart transplantation in one). Eighty percent of patients surviving cardiogenic shock were in New York Heart Association functional class I or II at 6 months. After 6 months, no patient had a myocardial infarction, four patients underwent a repeat revascularization procedure and one patient died (Fig. 2).

The 6-month angiographic follow-up rate was 92%. The patency rate of infarct-related arteries was 91%. There were three reocclusions of the infarct-related artery. The reocclusion was asymptomatic in two patients, whereas one patient experienced nonfatal reinfarction. Ten patients had >50% restenosis of the infarct-related artery. The incidence of >50% restenosis or reocclusion between hospital discharge and 6 months was 38%. The cumulative in-hospital and 6-month incidence of significant restenosis or reocclusion of the infarct-related artery was lower in patients with a stented infarct-related artery than in patients who underwent conventional PTCA alone (3 [20%] of 15 vs. 16 [67%] of 24, $p = 0.005$). As a consequence, a lower incidence of events related to restenosis or reocclusion of the infarct-related vessel was noted in patients with stenting of this vessel (Fig. 3).

Discussion

Study patients. Several observational studies (1-10) have examined the use of emergency PTCA in patients with AMI complicated by cardiogenic shock. All of these studies reported

Figure 2. Event-free survival curve after successful PTCA for 62 patients with cardiogenic shock. Cardiac events include death, myocardial infarction and any cardiac revascularization procedure.

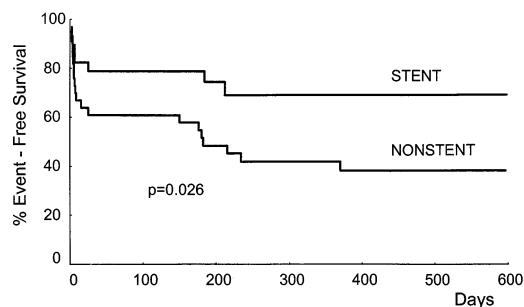
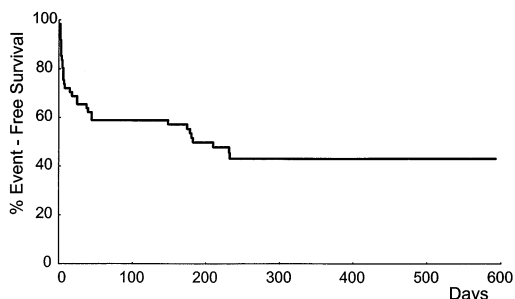


Figure 3. Event-free survival plotted for subgroups with a stented or a nonstented infarct-related artery. Cardiac events include death, myocardial infarction and infarct-related artery revascularization procedures.

decreased mortality after successful reperfusion of the infarct-related artery, but none clearly defined the criteria for the selection of certain patients for PTCA and others for conventional care, and a case selection bias may explain the favorable results described. The investigators from the Should We Emergently Revascularize Occluded Coronaries for Cardiovascular Shock? (SHOCK) registry (11) showed that 1) patients with AMI complicated by cardiogenic shock are a very heterogeneous group, and 2) that those selected to undergo coronary angiography had a lower mortality rate whether or not they underwent revascularization. The results of the SHOCK registry confirm that the selection process for emergency coronary angiography is such that the most critically ill patients are often not taken to the catheterization laboratory, whereas aggressive care is offered more often to the patients most likely to survive. This selection bias also applies to the results of PTCA in the Global Utilization of Streptokinase and TPA for Occluded Coronary Arteries (GUSTO I) trial (14), where PTCA was performed in only 15% of patients with shock on arrival and in only 20% of those who experienced shock after admission to the hospital. To obviate the confounding effects of selection bias on patient outcome, the ongoing randomized SHOCK trial will determine the benefit of early mechanical revascularization and of several new support devices in different subgroups of patients with cardiogenic shock.

In the present study this selection bias did not exist, because primary PTCA therapy was offered to all patients admitted with AMI within 6 h from symptom onset (or longer if there was evidence of continuing ischemia), and no upper age limit was used. Patients with the most profound shock were included; four patients died before they could reach the catheterization laboratory, and two died at the beginning of a failed PTCA attempt. Furthermore, patients treated with fibrinolytic agents were excluded from the study to avoid the confounding effects on results of previous different fibrinolytic treatments and of the criteria adopted to select patients for rescue PTCA.

The high incidence of cardiogenic shock in our study patients may be explained by the willingness of physicians to refer predominantly high risk patients for direct PTCA to our hospital because it has had a primary PTCA program since

1994 and serves as a regional referral center for several community hospitals and smaller neighboring hospitals within a 50-mile radius, as well as for the network of mobile coronary care units. A treatment bias with preselection of patients most likely to survive for referral to our institution is unlikely, because the selection process by clinicians is such that all patients with frank or incipient shock are immediately referred, including patients with a typically poorer outcome, such as those >75 years old or with the most profound shock.

Timing of shock. The temporal profile of cardiogenic shock in our study is different from that of other studies. In our study all patients had shock either on admission or within 1 h after admission, with a median interval between symptom onset and treatment of 3.3 h. In other studies, based on heterogeneous population samples, the median time from AMI onset to shock diagnosis was longer. The SHOCK registry investigators reported a median time of 8 h from AMI onset to shock diagnosis for the entire population of 251 patients registered (11); for the subgroup of 181 patients in whom shock developed within 24 h, the median time from AMI onset to shock diagnosis was 3.5 h (15). This registry also included patients with ST segment depression or mechanical complications, such as ventricular septal defect or mitral regurgitation, that could have lengthened the median interval between AMI onset and shock diagnosis. In the GUSTO I trial (14), which enrolled 41,021 patients with AMI, cardiogenic shock was identified in 2,972 patients (7.2%). Of the patients with shock, 89% experienced shock within 48 h of admission, most commonly in the setting of recurrent ischemia or reinfarction, whereas only 11% had shock on arrival. The small number of the latter patients may be a consequence of having excluded the majority of such patients from enrollment in clinical trials.

In our center the large majority of patients who undergo direct angioplasty are referred with the indication for immediate angiography and are directly admitted to the catheterization laboratory. This explains the short median time from symptom onset to treatment. The short delay from AMI onset to reperfusion is likely to have a beneficial effect on results.

Procedural results. The revascularization procedure success rate was 94%, and an optimal angiographic result (residual stenosis <30% associated with TIMI grade 3 flow and no dissection) was achieved in 85% of cases. These procedural results compare favorably with the 54% to 76% success rates of previous studies (1,9,10) of PTCA in patients with cardiogenic shock. The improvement in equipment and techniques and the availability of new devices, such as coronary stents, may explain these favorable immediate angiographic outcomes. In our study nearly half of the patients had primary stenting on the infarct-related artery because of a suboptimal or a poor angiographic result after dilation, and 21% of the patients had multiple stent implantation as a consequence of severe and diffuse disease of the infarct-related artery. Furthermore, all patients in the GUSTO I trial, and a substantial proportion (21% to 47%) of patients of other series (10,11,14) were previously treated with fibrinolytic agents and the procedural success rate in these studies could have been lowered by the

proved adverse effects of fibrinolytic agents on the PTCA results (16).

In-hospital outcome. The overall mortality rate of 26% and the rate of 21% for our patients with successful revascularization compare favorably with the 36% to 61% mortality rates from other series (1-11,14). The high rate of restoration of TIMI grade 3 flow that was associated with successful revascularization procedures may explain these differences, inasmuch as restoration of TIMI grade 3 flow is predictive of in-hospital survival and a reduction in infarct size, whereas TIMI grade 2 flow is associated with in-hospital outcomes similar to those of patients with occluded infarct-related arteries (TIMI grades 0 and 1) (17). The achievement of an optimal immediate angiographic result in the great majority of patients with successful recanalization may be explained by the high number of patients who had successful infarct-related artery stenting because of a poor or suboptimal angiographic result after conventional PTCA. Coronary stenting in the setting of AMI is feasible and provides better angiographic results than those of conventional PTCA alone, and it is associated with a good in-hospital outcome (18-20). In the subgroup of patients with a stented infarct-related artery, reocclusion of the artery consequent to stent thrombosis occurred in only one patient (3%), who died of fatal reinfarction. No patient with primary stenting had recurrent ischemia, whereas in the subgroup of patients who underwent conventional PTCA alone, the in-hospital recurrent ischemia or reinfarction rate was 21%. These results suggest a benefit of coronary stenting in patients with AMI complicated by cardiogenic shock as well.

Age, chronic coronary occlusion and completeness of revascularization were highly associated with mortality. The mean age was 63 years among survivors and 70 years among nonsurvivors. The association of chronic coronary occlusion with a higher mortality rate is not surprising, because patients with chronic coronary occlusion included patients with the most severe multivessel disease. Completeness of revascularization was inversely related to mortality. Most patients with complete revascularization had single-vessel disease; the small number of patients with multivessel disease who underwent complete revascularization makes it difficult to reach any definite conclusion about the real benefit of complete revascularization in patients with multivessel disease and cardiogenic shock. By multivariate analysis, age and other clinical and angiographic variables did not remain independent predictors of mortality. This observation is consistent with the SHOCK registry report (11), and it should be noted that the sample size analyzed may be too small to detect any statistical significance. Despite their higher mortality rate, the results of our study suggest that an aggressive intervention cannot be considered a contraindication in extremely aged patients with cardiogenic shock.

Long-term survival. There is a paucity of data concerning long-term survival after successful PTCA in patients with cardiogenic shock. Our long-term survival rate of 71% compares favorably with those of previous studies, where it ranged

from 45% to 54% (2,6,8,10). In the majority of survivors, major cardiac adverse events occurred within 6 months after AMI. Comparison of event-free survival curves of patients with a stented and nonstented infarct-related artery suggests that the benefit of primary stenting is maintained even through long-term follow-up.

Conclusions. Successful early mechanical revascularization by direct PTCA, including stent-supported PTCA, in patients with AMI complicated by early cardiogenic shock favorably affects the otherwise poor outcome in this patient group. Systematic direct PTCA can establish TIMI grade 3 flow in the great majority of patients presenting with AMI and early cardiogenic shock. As survival is clearly linked to reperfusion status, high performance criteria, including new devices, such as coronary stents, should be considered in ongoing randomized trials where PTCA therapy is being tested.

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